

Reformulating American Foreign Health Policy: TRIPS and Priority-Setting

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“It is more than probable that the socially most important inventions, say, of drugs or vaccines for the cure or prevention of cancer, would not be allowed to be exploited with the same monopolistic restrictions that are freely tolerated in the exploitation of patents on hair curlers, bottle caps, or television screens.”

Fritz Machlup, An Economic Review of the Patent System (1958)

Report for the Subcommittee on Patents, Trademarks and Copyrights of the U.S. Senate Judiciary Committee

“So if you take what’s supposed to be an exception for special circumstance, expand it to almost every country except the OECD countries, and then you expand it to every disease, *you’ve kind of blown a hole in the whole intellectual property regime.* And for example, Minister Malie of Lesotho, said that’s certainly not their intention, because they understand the role of intellectual property.”

USTR Robert Zoellick, Media Roundtable

Mauritius, January 16, 2003

Reformulating Policy

- U.S. political commitment of increased funding to treat HIV-AIDS a critical step toward confronting pandemic. Follow through on budget allocation essential
- In multilateral, regional and bilateral negotiating contexts focus of U.S. foreign health policy regarding developing countries is on enforcing TRIPS and TRIPS-plus patent and proxy-patent rules
- This policy focus is not in the U.S. or global public interest because it drains scarce financial resources, promotes poverty and fosters social and political instability. U.S. is pursuing contradictory foreign health policies
- U.S. policy should be redirected to assert primacy of public health needs and provision of treatment
- Competitive markets in the production and supply of pharmaceuticals are in the best interests of the United States and world community

Balancing Patents, TRIPS and Public Health

- Establishing a hierarchy between TRIPS Agreement-based obstacles and other obstacles to meeting public health needs is not productive. The issues and solutions are inter-linked:
 - Funding is required, but the cost of medicines is a key determinant of how much funding is needed and how far treatment will extend (i.e., program sustainability)
 - Acknowledged by President Bush in State of Union address applauding \$300/year ARV price as opening the possibility for treatment
 - Belatedly recognized by former President Clinton in recent activities in South Africa supporting generic production
 - Health infrastructure improvements are required, but infrastructure will not accomplish its objectives without medicines
 - For HIV/AIDS, unless the cost of medicines is brought down it is very unlikely that a globally sustainable program of treatment can be maintained

Patents, Prices and Public Health

- Provision of public health service is complex matter involving spectrum of regulatory issues (see F. Abbott, “Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines”, Duke 2002, Cambridge 2003)
 - Research and Development
 - Safety and Efficacy (including Liability)
 - Manufacturing Systems and Controls (GMP)
 - Intellectual Property
 - Procurement, Distribution and Dispensing
 - Health Care Personnel and Infrastructure
 - Financing
- Each incremental reduction in price of medicine brings additional consumers into the treatment market
 - From a basic economic and trade regulatory standpoint it is *thoroughly misguided* to suggest that patents and the price of medicines are not important to delivery of treatment

Three Basic World Pharmaceutical Supply Structures

- Competitive market in which significant number of suppliers bargain on basis of reducing production costs
- Oligopolistic market in which limited number of suppliers bargain on basis of exclusive rights
- Mixed market of oligopolist tier and competitive tier
 - Within each structure consumption/procurement can be undertaken through various structures (individual or aggregated)
- Most national markets represent mix - balance varies
 - U.S. represents high range of oligopolist dominance (absence of price competition)
 - Many national regulatory authorities regulate prices

Preferred Market Structure Varies Across Resource Settings

- U.S. prefers oligopolistic supply market largely unregulated as to price
 - Belief that patent system best mechanism for allocating risk capital in R&D
 - Basis for preference in its more extreme forms questionable
 - Originator industry propaganda successfully influences policy makers
 - Political contributions influence decisions
 - General perception that despite high costs individual patient-consumers are afforded access
 - Perception may be illusion – Members of Congress begin to perceive depth of constituent concerns, and state governors begin to rebel

Resource-Poor Settings

- For developing countries price is key determinant of access and treatment
 - National budget resources highly constrained
 - Large segments of population frequently without public assistance
 - Price affects sustainability and coverage of OECD donor funding
- Cannot bear costs of originator enterprises
 - Including high level expenditure on advertising and promotion, executive compensation, political lobbying

Patents, Price and HIV-AIDS

- HIV-AIDS antiretroviral treatment (ART) of potentially indefinite duration for millions of patients
- Global funding of ART limited in realistic best case
- Absent globally comprehensive ART program, medicines for opportunistic AIDS conditions also in high demand
- HIV-AIDS will strain public health budgets throughout the world, leaving more limited resources for prevention and treatment of other conditions
- Failure to treat HIV-AIDS will impose economic, social and political cost higher than costs of treatment

Patents, Prices and Basic Economics

- Patents grant right to holders to exclude third parties from entering market with equivalent (claim-infringing) products
- Right to exclude gives exceptional pricing power to patent holder
 - Extent of pricing power depends on variety of factors: demand-attraction, substitutes, market wealth, government policies
- From Pharma standpoint, objective of TRIPS Agreement was to capture patent rents from developing countries

Regulatory Data as Proxy Patent

- Pharma aware that patents will not for the near to medium term provide maximum exclusionary effect because of January 1, 1995 date of TRIPS entry into force
 - Medicines under patent in OECD prior to TRIPS often not under patent in developing countries
 - Solution for Pharma is to demand exclusion of reliance on regulatory submissions to block registration
- “Mailbox” filings authorized for medicines patent applications after January 1, 1995
 - Most developing countries have implemented patent protection, so mailbox applications processed
 - India principal supplier nation with no pharmaceutical product patent protection, but with mailbox (due to be activated in 2005)
- Blocking reliance on regulatory submissions potentially more exclusionary than patent protection because patents are subject to challenge on technical grounds

The Objective of the TRIPS Agreement

- The TRIPS Agreement was negotiated over continuous resistance from developing countries
 - See detailed negotiating history in TRIPS Resource Book, UNCTAD-ICTSD (<http://www.iprsonline.org>)
- U.S., EU and Japanese Pharma among principal demandeurs
 - Health constituencies (e.g., WHO) disengaged
- Combination of threats and incentives
 - Section 301 threats and sanctions, e.g., vis Brazil
 - Promises of reduction in EU agricultural subsidies, not fulfilled, replayed in Cancun
- UNCTAD Secretary General Ricupero: Developing countries had two choices on TRIPS, to be “boiled or fried”

Patents, Supply and Demand

- Suggestion made (Merck et al.) that patents not important because of limited patenting in some developing countries
 - Historic patenting pattern is consistent with common patent holder strategy of obtaining patents that block production in supplier countries and sales in countries with significant domestic markets (not limited to developing countries)
 - In Africa, antiretroviral medicines extensively patented, see MSF Drug Patents Under the Spotlight (2003)
 - Patents have consistently constituted obstacle to importing and producing low-priced medicines in Africa, including South Africa
- Focusing on least developed countries in Africa and elsewhere ignores supply side of pharmaceutical pipeline – if products cannot be manufactured in Brazil, India, China, South Africa, Egypt, where will generic competition come from?
- On importing side, Paragraph 7 of Doha Declaration (and WTO implementation) provide authority for least developed countries to “disapply” existing patents, allowing importation of generic medicines from, e.g., India (as well as local production). Critical to functioning of donor programs, but Pharma pressures must be resisted.

Patents, Prices and Basic Economics

- Evidence of effects of patents on prices of pharmaceutical products is extensive
 - See November 2002 Study of the Prices of the Top Selling Multiple Source Medicines in Canada, prepared by the Patented Medicines Prices Review Board (PMPRB)
 - **“Generic drugs are ordinarily introduced at a lower price than the brand name equivalent and consequently their availability may introduce competition in the market for that medicine which can play an important role in helping to contain increasing healthcare costs.”** (at 7-8)
 - The spread between generic and equivalent brand name drug prices varied depending on the number of generic versions of the drug available. **On average, the spread increased from about 25% when there were one to three generic versions available on the market to 45% when there were four or five generic sources.”** (at 2)
 - Canadian Study consistent with findings of WHO regarding introduction of generic competition (see A. Creese and J. Quick, “Differential Pricing and Feasibility”, WHO 2001)

Patents and Data Protection Will Be Persistent Obstacle to Effective Delivery of Health Services

- U.S. FDA Orange Book lists 94 pages with approximately 4,200 pharmaceutical patents
 - Many medicines covered by multiple patents
- Patents cover entire spectrum of disease prevention and treatment and will affect developed and developing countries
- USTR/PhRMA relies increasingly on data protection as “proxy patent”

Research and Development

- R & D on new drugs a global priority
- PhRMA “goose that lays the golden egg” promotion vastly oversimplifies R & D in pharmaceutical sector
- FTC Report on Patents and Innovation (October 2003) references National Institute for Health Care Management (NIHCM) study, “Changing Patterns of Pharmaceutical Innovation” (2002)
 - Present R&D incentive structure yielding very few significant innovations while imposing tremendous pharmaceutical budget expenditure increases
 - Most patents granted for minor changes to existing formulations often intended as means to block entry of generics

Research and Development

- Basic research is heavily subsidized by U.S. government and conducted predominantly in public institutions
 - NIH research budget \$28 billion in 2003
 - Research grants to universities, teaching hospitals, smaller scale private sector and larger scale industry. (See, e.g., NIH Contributions to Pharmaceutical Development (2000))
- PhRMA preferentially licenses NIH-funded research, paying very low royalties
 - “NIH's total Taxol-related spending [is] \$ 484 million through 2002. BMS's sales of Taxol totaled over \$ 9 billion from 1993 through 2002. BMS agreed to pay NIH royalties at a rate equal to 0.5 percent of worldwide sales of Taxol as part of a 1996 agreement to license three NIH Taxol-related inventions developed during the CRADA. Royalty payments to NIH have totaled \$ 35 million.” General Accounting Office Reports & Testimony, GAO-03-829, June 4, 2003, IAC (SM) Newsletter Database (TM) No. 7, Vol. 2003, IAC-ACC-NO: 104886946 (full text)

Non-Patent Driven R & D

- Inaccurate to suggest that development of important new technologies only occurs by operation of patent system (see W. Nordhaus, Invention, Growth and Welfare 1969)
- U.S. military research conducted on basis of armed forces procurement requirements and competitive R & D contracts (see, e.g., Joint Strike Fighter development)
 - Medicines technologies are strong candidates for procurement driven research contracting because treatment requirements are well-defined
 - Anti-Bioweapon R & D conducted on subsidy model

Research and Development

- Canada often cited by PhRMA as example of increased R & D following introduction of stronger patent protection
- PMPRB Performance Report for period ended March 31, 2002 indicates:

“Expenditures on ***basic research*** increased 2.5% in 2001, but its share of total R&D continued to decline from 17.8% in 2000 to 16.1% in 2001. This is the ***lowest proportion of total R&D spending on basic research ever reported by patentees*** since the Board began reporting such information in 1988.

The lion's share of R&D spending continued to be on applied research, \$604.8 million, or 59% of the total. Applied research is directed towards some practical application, comprising the manufacturing process, preclinical trials and clinical trials. ***Clinical trials totalled \$445.8 million in 2001 and accounted for 73.7% of total applied research expenditures and 44.1% of total current R&D expenditures.***” (emphasis added)

Research and Development

- Fully 90 percent of revenues of U.S. PhRMA companies in 2001 came from sales in the United States, Canada, Western Europe and Japan, while 0.3 percent came from sales in Africa. Very low portion of OECD R & D generated from patent revenues from developing countries. (PhRMA, Pharmaceutical Industry Profile 2003, Table 9)
- In 2001, U.S. PhRMA companies spent 0.1 percent of their worldwide R & D budgets in Africa (PhRMA Profile)

Developing Countries, R & D and Patents

- Very low global welfare gain from promoting extraction of monopoly patent rents on medicines from developing countries
- Costs to United States of rent-extraction not adequately factored into Pharma-based analysis
 - There is high potential external economic, social and political gain from encouraging price competition and lowering prices of medicines in developing countries
 - Reduced general public health expenditure
 - Increased economic stability
 - Increased social and political stability
- Particularly in cases where Pharma has not internally shouldered R & D costs (*e.g.*, NIH research), arguments in favor of maximizing rent extraction very weak

The Problem with U.S. Foreign Health Policy

- Each branch of government, various federal agencies and state governments responsible for developing and implementing domestic health policy
- Several federal agencies responsible for international health policy
 - Department of Health and Human Services, including Food and Drug Administration, National Institutes of Health
 - State Department (e.g., current HIV-AIDS policy)
 - U.S. Agency for International Development
 - Commerce and Defense Departments ancillary
- U.S. Trade Representative controls negotiation of rules and exercises disproportionate influence on medicines policy as well as general health system policy

USTR Control

- Extent of USTR control
 - Runs WTO TRIPS Council negotiations
 - Pursues international health policy as key agenda item of bilateral and regional trade negotiations
 - Activates role when major negotiations of interest occur at WHO
 - Takes direct interest in activities of World Bank, attempting to intervene in internal decisions

PhRMA Control of USTR

- U.S. PhRMA dominates development and execution of USTR foreign health policy
 - President of PhRMA (Alan Holmer) former Deputy USTR
 - Director-General of IFPMA (Harvey Bale) former TRIPS negotiator for USTR
 - In recent Paragraph 6 negotiations, USTR advised developing countries to deal directly with PhRMA companies
 - PhRMA publicly vetoed 16 December 2002 medicines deal

Imbalanced Foreign Health Policy

“Unhealthy”

- Health policy should not be equated with pharmaceutical industry policy
 - Depth of USTR/PhRMA role in foreign health relations should not be underestimated
- Interests of patients should take priority
- The best interests of the United States are not served by a foreign health policy that encourages poverty
 - U.S. foreign health policy should encourage poverty elimination, social and political stability
 - Cost to U.S. of adapting policy to further those objectives would be low

Developing Countries, R & D and Patents

- Licensing by NIH to domestic and foreign producers of patented pharmaceutical technologies (based on public funding) with payment of health needs-based royalty would accomplish multiple affirmative purposes
- Voluntary and compulsory licensing for export of private sector patented technologies with reasonable health needs-based royalty would provide marginal revenue to industry with modest opportunity costs

Competitive Markets

- Generic producers are motivated by same profit incentives as Pharma
 - Not a matter of distinction on moral grounds
 - Multiple generic producers drive down costs and prices
 - Best mechanism to allocate scarce resources is open competition for supply contracts based on marginal costs of production
 - Royalty payable to innovator based on capacity of recipient market, recovery of true R & D costs over period of patent term from aggregate global market and reasonable risk premium

Legislative and Regulatory Instruments

- Regulatory situation
 - Chapter 18 of Patent Act governing patent rights in federally funded inventions, in conjunction with
 - President's Memorandum for the Heads of Executive Departments and Agencies, dated February 18, 1983 and
 - Executive Order 12591
- Generally provide for vesting of title to patents based on federal funding in private researcher (35 USC 202(a)), with reservation of "march-in rights" by agency
 - Strong legislative and regulatory preferences for manufacture in the United States
- Under existing legislative arrangement NIH can at least use march-in rights to authorize U.S. generic producers to produce for export to developing countries (35 USC 203)
 - License would need to preclude originator patent holder from invoking patent in foreign jurisdiction
- Because preference for domestic production (35 USC 204) refers to "right to use or sell any subject invention in the United States", march-in rights can be granted for production outside U.S. for sale and use of product outside U.S.

Proposal to Implement Paragraph 6

- Congress should act to implement WTO Decision on Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health
 - Would allow compulsory licensing for export to countries with public health needs that have insufficient or no manufacturing capacity in the pharmaceutical sector
 - Would be open to all producers in the United States, whether Pharma or generic
 - Pharma appears concerned that foreign generic producers will capture market share. Paragraph 6 implementation would allow Pharma companies to compete in foreign generics markets with payment of royalty.
 - Production under public authority could be undertaken pursuant to government use exception to Patent Act (28 USC §1498), but level of compensation might be further addressed
 - For non-government use, Patent Act should be amended to establish TRIPS-consistent licensing procedure for production for export to be given effect through the Department of Health and Human Services.

Proposal to Amend Antitrust Legislation

- The Sherman Act expressly exempts U.S.-based anticompetitive conduct that affects only foreign markets (15 USCS § 6a), potentially inhibiting causes of action directed at abusive conduct in developing country markets
- PhRMA companies should face U.S. domestic liability for abusive conduct abroad because this may be only effective means to control such conduct
 - Abusive conduct in foreign public health markets damages U.S. foreign policy interests
- Exemption for conduct abroad may be misconstrued as “green light” for abusive conduct

Causes and Consequences

- The Pharma companies initiated a wholly unwarranted and extremely aggressive campaign against the government of South Africa as it attempted to implement its 1996 National Drug Policy
- That attack was based on the TRIPS Agreement and alleged patent rights
- The full extent of the negative consequences in terms of altering government policies may never be known, but there is no doubt that this action pre-occupied the public health system of the country for several years as the HIV/AIDS pandemic spread

Causes and Consequences

- Now Pharma says that we are paying too much attention to the TRIPS Agreement and patents, having just spent two years battling for a restrictive interpretation of Paragraph 6 of the Doha Declaration
- With due apologies, this is not an academic-esoteric debate
- Developing country governments do not have the power to effectively address Pharma. Effective controls must take place at the source of power, in the United States, European Union, Japan and Switzerland.

Reformulating U.S. Foreign Health Policy

- TRIPS-related policies are part of the mix of concerns that must be addressed
 - Enforcement of TRIPS and TRIPS-plus rules should be de-emphasized while patient interests and poverty alleviation prioritized
 - U.S. foreign health policy should *not* be equated with PhRMA profit maximization policy
- USTR role should be reduced in relation to Health and Human Services
- Competitive market in pharmaceutical supply should be promoted